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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,663	02/27/2002	A. K. Gunnar Aberg	559P017	3512

7590 06/15/2004
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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,663

Applicant(s)

ABERG ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-22-2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 6-15, 18-20 are pending. Claims 4, 5, 16, 17 have been canceled according to the amendment filed on 7-25-2003. Claims 2, 3 have been cancelled according to the amendment filed on 3-22-2004.

Claim Rejections - 35 USC § 102

2. The 35 U.S.C. 102(b) over Polivka I (CS 263993) or Polivka II (Coll. Czech. Chem. Commun. 1989, 54(9), 2443-69, PTO-1449) is withdrawn because the claims have been amended to a pharmaceutical composition comprising the S-norketotifen, thereby setting demarcation from the prior art composition comprising the precursor ketotifen.

Claim Rejections - 35 USC § 103

3. The 103(a) rejection over Polivka I (CS 263993) or Polivka II (Coll. Czech. Chem. Commun. 1989, 54(9), 2443-69, PTO-1449) in view of Le Bigot (Life Sciences, 40, 883-890, PTO-1449) and Bourquin (3862156, PTO-1449) and Kofler (Experimental Chemistry. Organic Chemistry and Reaction. Pages 504-505, PTO-1449) is maintained since it is applicable for the amended claims 6-15, 18-20 .

While Polivka I or II does not specifically disclose the method of using S-enantiomer of norketotifen as recited in the instant, administration of the prodrug, the S enantiomer of ketotifen, to an animal would lead to the corresponding S-norketotifen, the known metabolite in vivo (Le Bigot, Life Sciences, 40, 883-890, PTO-1449, page 889, Fig. 2). The lack of sedative effect as recited in the instant is inherent in the S-norketotifen.

While the above references do not recite the topical, dermal, transdermal, rectal etc. administration or different physical forms of the composition as recited in the instant claims 13-15, 18-20, such formulations and modes of administration are well known in the pharmaceutical art and are routines for one of ordinary skill in the art. The addition of

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another active ingredient of the same use, such as another antihistamine, in the composition comprising the antihistaminic S-norketotifen for a more effective formulation is prima facie obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 112(2)

4. The rejection for Claim 20 under 35 U.S.C. 112, second paragraph, is withdrawn because the amendment has obviated the rejection.

Claim Rejections - 35 USC § 112(1)

5. The rejection under 35 U.S.C. 112, first paragraph is withdrawn for claims 8-12 in view of the amendment obviating the rejection, but it is maintained for claim 7, 13-15, 18-20 for reasons of record.

The instant method is directed to using the histamine H1 receptor binding compound for preventing or treating a respiratory disorder, allergic disorder, a dermal disorder, a gastrointestinal disorder or an ocular disorder. However, each of these is a class disorders encompassing diseases of diverse origins. For example, according to the Merck Manual (11th Edition), the following diseases or disorders are described in Section 18, Respiratory (page 1266): pneumonia, pulmonary emphysema, atelectasis, tuberculosis, neoplasms, hypoxia....etc., each has different origins and requiring different treatments. One of ordinary skill in the art would have no basis to expect an H1 ligand to be effective in preventing or treating all these different respiratory diseases.

Claim 20 is directed to a method of claim 7 comprising administering to a mammal in need thereof, a S-norketotifen and one or more drugs selected from a laundry lists of different classes of active ingredients, a full description of which are not found in the specification. Furthermore, it is well known in the art that synergism, co-action or antagonism would occur among the multiple active ingredients.

Since sufficient guidance have not been provided in the specification, undue experimentation would be required to use the invention as claimed.

Claim Rejections - 35 USC § 102

6. The rejection under 35 U.S.C. 102(a) over Aberg I (WO 98/56381) or Aberg II (WO 98/43640, PTO-1449) is maintained because it is applicable to amended claims 1, 6-15, 18-20.

Aberg I (page 2) or II (page 6) discloses norketotifen, which can only be in the form of racemate or stereochemical isomers. The pharmaceutical composition comprising norketotifen in Aberg I or II anticipates the instant pharmaceutical composition comprising the S-norketotifen, since the instant 'comprising' would allow for the presence of the R- norketotifen (or a racemate) as in the prior art composition.

The instant method of using S-norketotifen free of sedative side effect would inherently flow from the prior art method of using norketotifen in the treatment of ocular disease or as an antihistamine or an anti-inflammatory agent without sedative effect.

Double Patenting

7. The rejection for Claims 7, 9, 10, 12, 13-15, 18-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6207684 (the US equivalent to WO 98/56381) is maintained for reasons of record. The rejection is applicable to the amended claim 1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented method of using norketotifen for treating an ocular disease with less sedative effects (column 1, lines 57-62; Claims 1-7) anticipates the instant claims.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

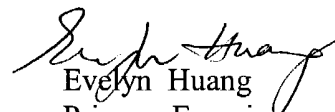
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625